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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/289,576	04/09/1999	RICHARD C. ALLEN	398802000600	8803

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MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

FALK, ANNE MARIE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/289,576

Applicant(s)

ALLEN ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 9-12, 19-36 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 9-12, 19-36 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/23/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed September 23, 2004 (hereinafter referred to as "the response") has been entered. Claims 1, 5, and 9-11 have been amended. Claims 4, 8, and 17 have been cancelled. Claim 44 has been newly added.

Accordingly, Claims 1-3, 5, 6, 9-12, 19-36, and 44 remain pending in the instant application.

Claims 19-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in Paper No. 10.

Accordingly, Claims 1-3, 5, 6, 9-12, and 44 are examined herein.

The rejection of Claim 17 under 35 U.S.C. 112, second paragraph is withdrawn in view of the cancellation of this claim.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 23, 2004 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-3, 5, 6, and 9-12 stand rejected and Claim 44 is rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 2-6 of the Office Action mailed 5/7/01, on pages 2-6 of the Office Action mailed 2/27/02, on pages 3-6 of the Office Action mailed 11/18/02, and on pages 3-4 of the Office Action mailed 7/2/03, on pages 2-5 of the Office Action mailed 3/23/04, and for further reasons as discussed herein, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At page 8, paragraph 3 of the response, Applicants assert that the rejection relates to the effective scope of the enablement regarding several aspects of the claimed invention. Contrary to Applicants' assertion, however, no scope of enablement has been indicated and the rejection covers the entire scope of the claimed invention.

At page 8, paragraph 4 of the response, Applicants point out that the claims have been amended to narrow the scope of the cell types that may be used in carrying out the claimed invention. However, no arguments are offered relating to enablement for use of the wide variety of cell types mentioned in the claims for producing a therapeutic effect in a schizophrenic patient.

At page 9, paragraph 3 of the response, Applicants argue that the prior art demonstrates the association of a deficit in prefrontal dopamine function and schizophrenia and the association of deficits in delayed-response tasks observed in nonhuman primate models of prefrontal dopamine deficiency. Applicants point to Brozoski et al. (1979; not of record) for teaching that administration of L-DOPA to rhesus monkeys having 6-OHDA induced lesions in the dorsolateral prefrontal cortex improved cognitive function. Applicants further point to the post-filing art of Fernandez-Ruiz et al. (1999) for teaching that L-DOPA administration to MPTP-lesioned rhesus monkeys resulted in improvement of cognitive functions of the prefrontal cortex. However, the MPTP lesion was in the striatum (producing a model for Parkinson's Disease, not schizophrenia), not the prefrontal cortex and the reference clearly discloses that

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the dopamine deficiency was in the striatum, not the prefrontal cortex (page 105, column 1, paragraph 1). Nevertheless, studies that teach administration of L-DOPA do not provide specific guidance with regard to the claimed invention which is quite distinct, involving administration of cells that produce dopamine or a dopamine precursor. The cells must produce dopamine or a dopamine precursor at the appropriate location, in an amount sufficient to alleviate a symptom of schizophrenia. The references cited do not provide evidence of an enabling disclosure for such a protocol.

At page 10, paragraph 5 of the response, Applicants cite Watts et al. (2003) for teaching that implantation of a cell/support complex in a dopamine deficient region of the brain of patients with Parkinson's disease ameliorates symptoms associated with dopamine deficiency in the region. Applicants conclude that the specification in combination with that known in the art enables the skilled artisan to make and use the invention as claimed and that any additional experimentation is within the level of ordinary skill in the art and not undue. First, it is noted that the reference relied upon is post-filing art and as such cannot be used to supplement the teachings of the specification. One of skill in the art would not have had the benefit of the teachings of Watts et al. (2003) at the time of the invention. Second, a teaching relating to dopamine replacement therapy for Parkinson's disease does not provide guidance for treatment of a patient with schizophrenia, which has its own distinct etiology. As discussed in the previous Office Actions (page 3, paragraph 2 of the Office Action mailed 7/2/03 and page 4, paragraph 1 of the Office Action mailed 3/23/04), while increasing dopamine levels within the prefrontal cortex may be desirable, the instant specification does not teach how to generate dopamine levels that are sufficient to reduce a symptom of schizophrenia. Considerable experimentation would be required to go from a suggestion to increase dopamine activity in the prefrontal cortex as a treatment for schizophrenic patients to actually providing an enabled protocol for achieving the desired treatment effect. Even for those diseases where the etiology is understood quite well (e.g., diabetes), development of cell therapy protocols has been an enormous challenge. In view of the state of the art and unpredictability in the art,

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for reasons of record, such experimentation is not considered routine, but rather would rise to the level of undue experimentation.

Given the lack of applicable working examples, the limited guidance provided in the specification, the broad scope of the claims with regard to the wide variety of cell types that could be used, and the unpredictability for achieving a therapeutic effect in a schizophrenic patient upon the transplantation of a cell/support complex, undue experimentation would have been required for one skilled in the art to practice the claimed method of the invention in a subject for therapeutic benefit.

Thus, the rejection under 35 U.S.C. 112, first paragraph, is maintained.

Conclusion

No claims are allowed.

This application contains claims 19-36 drawn to an invention nonelected without traverse in Paper No. 10. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER